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10/807,590	03/24/2004	Mark Girard	10142/04201	3798

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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/807,590
Filing Date: March 24, 2004
Appellant(s): GIRARD ET AL.

Oleg Kaplun
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03-01-2008 & 04-01-2008 appealing from the Office action mailed 11-01-2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The amendment after final rejection filed on 01-02-2008 has been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,892,518	Cupp et al.	01-1990
5,542,923	Ensminger et al.	08-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-10, 13-16, 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cupp et al. (USPN 4,892,518), and further in view of Ensminger et al. (USPN 5,542,923).

Cupp et al. discloses an F-shaped connector for a dual well port, comprising: a trunk including first and second connector lumens extending therethrough, distal ends of each of the first and second connector lumens being connectable to proximal ends of separate catheter lumens; a first arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the first connector lumen, a proximal end of the arm portion of the first connector lumen being fluidly connectable to a first well of the dual well port; and a second arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the second connector lumen, a proximal end of the arm portion of the second connector lumen being fluidly connectable to a second well of the dual well port, wherein the first and second connector lumens are separate from one another so that fluid from the first well does not mix with fluid from the first well before reaching the distal ends of the first and second connector lumens (see figures 2, 7, 11A and entire reference), but fails to teach the first arm separated from the housing by a gap.

Ensminger et al. discloses an F-shaped connector for a dual well port, comprising: a trunk including first and second connector lumens extending therethrough, distal ends of each of the first and second connector lumens being connectable to proximal ends of separate catheter lumens; a first arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the

first connector lumen, a proximal end of the arm portion of the first connector lumen being fluidly connectable to a first well of the dual well port; and a second arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the second connector lumen, a proximal end of the arm portion of the second connector lumen being fluidly connectable to a second well of the dual well port, wherein the first and second connector lumens are separate from one another so that fluid from the first well does not mix with fluid from the first well before reaching the distal ends of the first and second connector lumens (see figure 4 and entire reference) and teaches a gap (the space between the first and second arm [92, 92`]).

Therefore at the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Cupp et al. with the teachings of Ensminger et al., since the limitations not taught in Cupp et al. is an obvious matter of design choice to one skilled in the art. Applicant fails to disclose any criticality and/or unexpected results and even teaches that one of ordinary skill would understand how to modify the device depending on the medical situation (applicant's specification paragraph 0012). Further more, it appears that the invention would perform equally well with any spacing between the first and second arm, whether it be an opening or just a space between the first and second arm, as taught by Cupp et al. (in reference number 161) or the gap between the housing as taught and shown in figure 4 of Ensminger for the reasoning that the space still serves the same function, which is to maintain separate lumens to prevent the medicaments from mixing. Hence forming a space

between the housing and the arms are a mere obvious modification that would require routine skill in the art.

2. Claims 1-10, 13-16, 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ensminger et al. (USPN 5,542,923).

Ensminger et al. discloses an F-shaped connector for a dual well port, comprising: a trunk including first and second connector lumens extending therethrough, distal ends of each of the first and second connector lumens being connectable to proximal ends of separate catheter lumens; a first arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the first connector lumen, a proximal end of the arm portion of the first connector lumen being fluidly connectable to a first well of the dual well port; and a second arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the second connector lumen, a proximal end of the arm portion of the second connector lumen being fluidly connectable to a second well of the dual well port, wherein the first and second connector lumens are separate from one another so that fluid from the first well does not mix with fluid from the first well before reaching the distal ends of the first and second connector lumens (see figure 4 and entire reference) and teaches a gap (the space between the first and second arm [92, 92`]), but fails to teach the specific angels of the first and second arms.

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify the device of Ensminger et al., since the limitations not taught in Ensminger et al. is an obvious matter of design choice to one skilled in the art. Applicant fails to

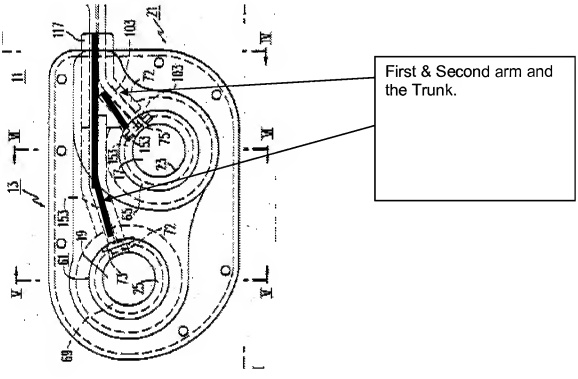
disclose any criticality and/or unexpected results and even teaches that one of ordinary skill would understand how to modify the device depending on the medical situation (applicant's specification paragraph 0016). Further more, it appears that the invention would perform equally well with any angle between the first and second arm and the tubing connected to the first and second arm, the reasoning that the angle of the arms and tubing doesn't change the overall concept of the invention, which is to provide a compact delivery device that allow separate medicament to be injected into the body, wherein the separate medicament is prevented from mixing together. Therefore, the modifications to the first and second arms would be an obvious one and would only take routine skill in the art to fulfill the requirements of the claims.

(10) Response to Argument

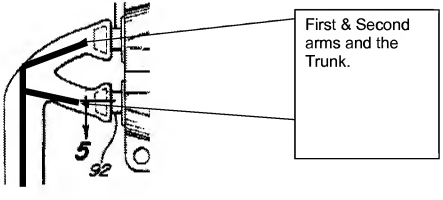
The applicant and examiner disagree on whether the prior art of record teaches a "substantially F-shaped flow element" and how to interpret such a limitation. The examiner interprets the claims as broadly as reasonably possible, and therefore came to the conclusion that the prior art could be interpreted as substantially F-shaped flow elements. According to applicant's own specification on page 8, paragraph [0016] the substantially F-shaped flow elements would have substantially parallel arms projecting for a common trunk and the arms would be projecting from the trunk at an angle between 15 to 75 degrees (with respect to the longitudinal axis of the trunk). Therefore from this description and the claim language of "substantially parallel" the examiner

determined that the "entire" first and second arm needs only to resemble two parallel arms. This can be seen in both references below.

Cupp et al.



Ensminger et al.



The examiner would also like to note that the term substantially that is before the "F-shaped flow element" and "parallel" allows the examiner to find a structural element that is close to those limitations but not exactly parallel and F-shaped. This can be confusing especially when dealing with terms like parallel because the definition of parallel is two lines that never intersect, therefore if the two lines are substantially parallel, then the lines will intersect but at what point, and how much weight would be given to parallel if the lines intersect thus making the lines not parallel. The examiner would also like to state that the portions of the arms that are connected to the ports of the reservoir wells are substantially parallel to each other, thus fulfilling the claimed limitation of the first and second arm being substantially parallel.

With regards to the lack of criticality arguments, the examiner is confused by these arguments. The examiner was stating that the applicant fails to provide any reasoning or criticality to why certain angles or shaped are being used and because of this it seems that one of ordinary skill in the art would be able to use routine skill to modify the prior art to encompass the claimed invention. The examiner was trying to provide rationale for his obvious rejection. The examiner would like to note that further rationale for an obvious rejection would be modifying the prior art because of the rationale of "obvious to try" reasoning.

With regards to the dependent claims, the examiner felt that the prior art clearly disclosed the subject matter. With regards to claims 2 & 8 as well as other claims that deal with the cross section of the lumens or the partition in the trunk; it can clearly be seen in figure 1, 2 and 9-9E (Cupp et al.) or figures 4 and 28 of (Ensminger). With

regards to valves, once again both references disclose in the specification as well as clearly show the valves in the figures. Cupp et al. discloses valves as reference numbers 127 and 131, while Ensminger discloses valves as reference numbers 38, 40 as leaflet valves and other valves 196, 198 as well as being shown in figures 1A, 5, 9, 15, 16, 23, 27, 31, 39.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Matthew DeSanto

/Matthew F DeSanto/

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